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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,410	05/07/2001	Gregory R. Reyes	4600-0183.26	2902
22918	7590	05/27/2005	EXAMINER	
PERKINS COIE LLP P.O. BOX 2168 MENLO PARK, CA 94026			MOSHER, MARY	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 05/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/851,410

Applicant(s)

REYES ET AL.

Examiner

Mary E. Mosher, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/14/05, 4/11/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/14/2005 has been entered.

Election/Restrictions

In the paper filed 12/11/2003, applicant elected without traverse group II, ORF2 protein or fragment. Claims 42-61 have been examined only to the extent that they read upon compositions comprising ORF2 peptides. It is noted that the claims literally encompass ORF3 peptides, because one could prepare an ORF3 peptide from an expression vector which comprises the ORF2 sequence recited in claim 42 or 54, or from a vector which comprises the hybridizing sequence recited in claim 45.

Claim Rejections - 35 USC § 112

Claims 45-61 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for that part of the claims which involve ORF2-homologous peptides and fragments which are specifically immunoreactive with antibodies present in individuals infected with HEV, the specification, does not reasonably provide enablement for peptides encoded in all reading frames or peptides which meet the structural limitations of the claims but fail to react with HEV antisera.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The only uses taught for peptides in the specification are diagnosis of HEV infection and for immunization against HEV. However, the claims encompass peptides which are translated from either strand and any reading frame, including peptides which the specification states "are probably not expressed," see page 14. Since the specification does not provide any guidance on how to use all of these peptides, it is concluded that undue experimentation would be required to use the full scope of the products claimed.

In response to a similar rejection, applicant argues that the specification teaches a broad range of diagnostic and therapeutic applications on specification pages 59 through 70. However, all of the applications rely upon immunological cross-recognition between the peptides and HEV, and the claims, as written, include peptides which lack that essential functional characteristic. Therefore the argument is not convincing.

In addition, claims 47, 51, 57 and 61 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunogenic or immunoreactive composition, does not reasonably provide enablement for a vaccine, for reasons of record.

Double Patenting

Claims 42, 44, 45, 48, 49, 52-55, 58-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-10, 24-29 of U.S. Patent No. 5824649. Although the conflicting claims are not identical,

they are not patentably distinct from each other because the instant claims encompass previously patented HEV Orf2 proteins and fragments.

Claims 45, 54, 55, 58, 59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6214970 or 6291641 or 5770689, or claims 1, 3, 4 of U.S. Patent No. 5885768. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant "homologous" and fragment claims encompass the previously patented fragments.

Claims 42-61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5741490. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the previously patented compositions.

Claims 42-61 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 10/165868. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant composition claims encompass the copending composition claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 42-61 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22, 23 of

compending Application No. 09/769066. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant composition claims encompass the compending vaccine composition claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

5/25/05


MARY E. MOSHER, PH.D.
PRIMARY EXAMINER